

Part 4. Registration Guidelines

Part 4.1

Checksheet for Programs Seeking to Establish Early Defibrillation Services

Select and designate an area to place and store AED's and needed supplies. The space should have immediate access to an operable telephone for the purpose of summoning EMS in the event of a medical emergency.

Develop written operational policies and procedures which address the operation and maintenance of needed equipment, responsibilities of personnel associated with the service and notification of the needed public safety agencies (ie. daily readiness checks, plans to identify performance problems, when and how to contact 911, daily maintenance checks on equipment and supplies).

Obtain the services of a Service Medical Director as described in Section 4.2 E of this document. The Service Medical Director shall complete the "Service Medical Director Agreement Form" and return said form with the service's application for registration.

Assure that all service personnel are of minimum age and are trained in an approved AED training program. Develop a quality improvement program to assure continued quality of the program.

Assure that the AED service acquires and maintains a valid registration at all times while providing this care.

Acquires Automated External Defibrillator(s) which has/have been approved by the United States Food and Drug Administration.

Display the "Registration To Operate Certificate" in a public area of the Early Defibrillation Service.

Assure completion of an "Incident Report" with three copies as specified in Section 4.2 D of this document.

Part 4.2 Registration

A. Early Defibrillation Service Program Standards

"Early Defibrillation Service" is a term used by the Office of EMS to define persons, organizations and/or programs authorized through registration to operate automated external defibrillators.

1. Chapter 4, Article 2.1 of Title 32.1 of the Code of Virginia (1950) vests authority for the regulation of early defibrillation services in the State Board of Health. This authority includes the regulation of Early Defibrillation Programs by type of service rendered and specify the medical equipment, supplies and personnel required. The law (see Appendix) further requires the use of registration, reporting and inspection for compliance.
2. The Office of Emergency Medical Services shall administer these regulations as delegated by the Board of Health.
3. Early Defibrillation Services already providing comparable programs within the Commonwealth are also required to comply with these regulations within 180 days from the date of adoption by the Board of Health.
4. The Early Defibrillation Service is a program intended solely for the immediate response to the location of a suspected cardiac or respiratory arrest for the delivery of life support until the arrival of higher trained EMS or other medical personnel qualified to provide for patient care and/or transport.
5. Early Defibrillation Services are limited to the provision of these specific services. Any other emergency medical services provided by such agency shall be subject to licensure under the separate rules and regulations for that purpose. An Early Defibrillation Service and its agents shall not provide services beyond the agency's registered capability.
6. No Early Defibrillation Service shall refuse to provide required services based on the inability of the patient to provide payment of services rendered by the service.
7. All Early Defibrillation Services shall ensure that services are available to the agency population within their regular operating areas and hours on a continuous basis.
8. All Early Defibrillation Services shall insure that telephone service is readily available at all times for notification of the local emergency medical services agency in the event of a medical emergency. In cases

where the automated external defibrillator is carried in a service operated vehicle, such service vehicle must be equipped with a method of notifying EMS via radio/telephone (cellular, etc.) or service operated two-way radio system.

B. Notification Requirements

1. Early Defibrillation Services shall be responsible for notifying and keeping current the location and extent of its operations to:
 - a. the EMS Agency with primary responsibility for providing emergency response and ambulance transport services.
 - b. the Public Safety Answering Point responsible for dispatch of EMS response. The dispatch may be provided from a municipal dispatch center, law enforcement, fire or independent EMS agency.
 - c. the Office of EMS of any changes to the service's status such as changes in trained personnel, additional defibrillators being put in service or changes in Service Medical Directors.

C. Operational Policies

1. The Early Defibrillation Service shall have written operational policies and procedures which shall be subject to and available for inspection by the Office of EMS. These policies should at a minimum address:
 - a. the operation and maintenance of the services provided by the Early Defibrillation Service including equipment and facilities.
 - b. the responsibilities of personnel associated with the service as limited by registration.
 - c. notification procedures in the event of an incident.

D. Records and Reports

1. The following records and reports shall be prepared and maintained for a period of not less than five (5) years:
 - a. Current personnel records of each Early Defibrillation Service member or employee including a file for each which provides documentation of training and qualifications including evidence of certification.

- b. Records of each automated external defibrillator currently in use to include maintenance records and records of safety inspections.
- c. Records of Early Defibrillation Service activity including call reports which specifically identify agency personnel, dispatch records and summary data.
- d. An "Incident Report" shall be completed for each instance where the Automated External Defibrillator is deployed and eventually applied to an actual or potential patient. The report shall be completed on forms provided by the Office of EMS and shall be in three parts
 - 1. Original COPY - Maintained by the Early Defibrillation Service as described above.
 - 2. COPY 2 - Forwarded to the Office of EMS for review not more than 15 business days following the patient care incident.
 - 3. COPY 3 - Provided to the responding EMS agency which assumed care of the patient. The copy of the completed report may be provided during the patient care incident or at a later time; not more than 5 business days following the patient care incident.

E. Service Medical Director

- 1. All Early Defibrillation Services shall be required to have a minimum of one Service Medical Director. The Service Medical Director shall be a licensed physician in the Commonwealth of Virginia and shall provide proof of unrestricted Virginia licensure with the service registration application.
- 2. The responsibilities of the Service Medical Director shall include but not be limited to:
 - a. development and approval of service protocols
 - b. the establishment of cooperative agreements with the participating Early Defibrillation Service and local EMS agencies.
 - c. functioning as a resource to the agency in planning, scheduling and participation in the initial training and continuing education programs for the service's personnel.

- d. the development of a mechanism to assure the continued competency of service personnel to include periodic training and semi-annual skill proficiency demonstrations monitored by the Service Medical Director or his/her designee.
- e. periodic review of service activities as they relate to patient care.
- f. establishment of any other rules or activities needed to insure the delivery of proper patient care within the service's scope of practice.
- g. Cooperating with local public service agencies for the purpose of carrying out routine quality assurance programs which relate to the service's activities.

F. Early Defibrillation Service Program Responsibilities

1. Ensures that all defibrillation and related equipment are maintained by the service.
2. Ensures the following equipment and supplies are available for each defibrillator in service.
 - a. Pocket mask or other CPR barrier devices which are designed to limit transmission of bloodborne pathogens or other bodily fluids between the rescuer and patient.
 - b. CDC recommended protective gloves in quantities and sizes for all personnel on duty.
 - c. First Aid Kit of durable construction and equipped with the supplies listed above.
3. The Service Medical Director shall be responsible for insuring sufficient training has been provided to authorized service personnel in the use of any additional first aid equipment used by the service. The specifications and quantities of such other supplies shall be determined by the Service Medical Director.
4. Every Early Defibrillation Service shall publicly display the registration to operate in the headquarters of the service.

G. Sanitation

1. All Early Defibrillation Services shall observe the following sanitation guidelines:

- a. Keep clean and sanitary all storage areas, equipment and supplies.
- b. Use plastic bags, covered containers or compartments for storage of soiled supplies and used disposable items. Red or orange bags marked as "Biohazard" should be used for infectious waste.
- c. Keep all exterior device surfaces clean.
- d. All used airway devices shall be stored properly and disposed of after use. Reusable items shall be sterilized in accordance with current acceptable medical technology.
- e. Waterless handwash shall be available.
- f. Bleach or other disinfectant solution (as approved by the CDC) shall be available for cleaning.

H. Exempt from Regulation

- 1. Medical care facilities such as hospitals, doctor offices and other specialty care centers are exempt from these regulations.
- 2. Commercial carriers such as aircraft, ground transportation vehicles such as buses and trains are deemed exempt from these regulations.

I. Law Enforcement Agencies

- 1. Law Enforcement agencies as defined under Section 9-183.14 of the Code of Virginia may hold a single registration for all locations, personnel and vehicles operated by such agency for the purpose of providing Early Defibrillation Service to the general public within such agency's area of law enforcement jurisdiction. This does not exempt any such Law Enforcement agency wishing to provide EMS response and patient care beyond the scope of it's Early Defibrillation Service registration from the requirements for EMS Agency Licensure under the applicable regulations issued by the Board.

J. Application for Registration

- 1. The Early Defibrillation Service shall file written application on forms contained within this packet for a registration with the Office of EMS. Required forms shall be mailed to:

Virginia Office of Emergency Medical Services
1538 East Parham Road
Richmond, Virginia 23228

2. The applicant shall include payment of a registration fee of twenty-five dollars (\$25) with their application for registration in the form of a personal, company or cashier's check; or pre-paid money order made payable to the Office of Emergency Medical Services (cash payments will not be accepted).
3. The Office of EMS may use whatever investigative means necessary to verify any or all information contained within the application.
4. A minimum of sixty (60) days should be allowed for verification and processing of the agency registration.
5. The issuance of a registration shall not be construed to authorize any Early Defibrillation Service to provide any other emergency medical services or to operate without a franchise in any county or municipality which has enacted an ordinance requiring such.
6. Each Early Defibrillation Service registration shall be valid for a period of four years from the date of issuance unless and until revoked or suspended by the Office of EMS.
7. Registrations shall not be transferable.

K. Renewal of Registration

1. Application for renewal shall be submitted a minimum of sixty (60) days prior to expiration on forms provided by the Office of EMS.
2. The applicant shall include a payment of a registration fee of twenty-five (\$25) with their application for registration in the form of a personal, company, cashier's check, or money order payable to the Office of EMS (cash payments will not be accepted).
3. The Early Defibrillation Service shall be in compliance with all standards set within these guidelines to qualify for renewal of registration.

L. Modification of Registration

1. Any changes in the location of operation or in any of the conditions that may apply to the Early Defibrillation Service shall necessitate the modification of the registration.
2. Modification of registration shall be initiated by the Early Defibrillation Service by requesting the modification in writing to the Office of EMS.
3. The registrant shall be notified in writing of the approval within thirty (30) days of receipt of the request.
4. The registrant shall return the unmodified registration to the Office of EMS within ten (10) days of receipt of the modified registration.

M. Personnel Training Requirements

1. Personnel involved in the Early Defibrillation Service shall be subject to the following general requirements:
 - a. Be a minimum of sixteen (16) years of age.
 - b. Shall successfully complete training in cardiopulmonary resuscitation and in the use of automated external defibrillation in a course which has been approved by the Board of Health (a list of approved courses is included with this packet).
 - c. Any individual currently certified in Virginia as an EMS First Responder, Emergency Medical Technician or an equivalent approved by the Office of EMS shall be deemed as meeting this training requirement.

N. Standards of Conduct

1. All personnel shall comply with the requirement of the Rules and Regulations Governing Early Defibrillation Services in Virginia.
2. All personnel shall comply with all federal, state, and/or local laws applicable to their operations.

3. Personnel and Early Defibrillation Services shall be responsible for providing patient care information as required by the Rules and Regulations and State law.

O. Provision of Care

1. Personnel shall be responsible for providing automated external defibrillation consistent with their levels of training and within the scope of the Early Defibrillation Service with which they may be affiliated.
2. No Early Defibrillation Service shall refuse to provide required services based upon the inability of the patient to provide means of payment or based upon the race, sex, religion, age or national origin of the patient.
3. Personnel shall be authorized to withhold treatment from patients in respiratory and or cardiac arrest only when provided with documentation that the patient involved has a valid Virginia "Do Not Resuscitate Order" or a valid "Do Not Resuscitate Order" issued by a state which has a reciprocal agreement with Virginia.
4. Medical information concerning any individual is confidential and shall not be shared or disclosed except for continuing medical care or for investigations by the Department of Health.
5. All decisions not to transport a patient shall be fully documented by the Early Defibrillation Service if no otherwise licensed EMS agency is present at the scene when such refusal of care occurs.

Personnel and services shall not leave a patient without assuring that an equal or higher level of care is provided. Informed consent shall be obtained or informed refusal of care shall be documented.